A randomized, placebo-controlled trial to evaluate the efficacy and safety of novel mixtures of 0.01% or 0.02% cyclosporine A with 3% trehalose in dry eye syndrome

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Trehalose has been known to stabilize bilipid membranes and proteins against desiccation, and to have a protective effect against desiccation and oxidative insult in the mammalian eye, which has been made into some tear preparations. In this trial, the efficacy and safety of a novel mixture of 0.01% or 0.02% cyclosporine A (CsA) with 3% trehalose in dry eye were analyzed. Dry eye patients with corneal staining score more than 2 were randomly assigned to receive mixture of 3% trehalose and topical 0.01% (low dose treatment) or 0.02% (high dose treatment) CsA, or placebo to be administered twice daily for 12 weeks. The primary efficacy outcome was a change from baseline in corneal fluorescein staining scores at week 12, and changes at week 4 and 8 were reported as secondary endpoints. Additional endpoints included score changes from baseline in conjunctival staining, strip meniscometry, tear breakup time (TBUT), Standard patient evaluation of eye dryness questionnaire (SPEED) at week 4, 8 and 12 and ratio of 100% clearance in corneal staining. At week 12 of treatment, corneal staining scores were improved in patients treated with high-dose treatment, with significant difference compared to the placebo treatment (p=0.0361). There was no significant difference between low-dose treatment and placebo in corneal and conjunctival staining, strip meniscometry, TBUT, SPEED at week 4, 8 and 12. There were no significant difference between high-dose treatment and placebo in corneal staining at week 4, 8, conjunctival staining, strip meniscometry, TBUT, SPEED at week 4, 8 and 12. Ratio of 100% clearance in corneal staining were 53.13% in placebo, 55.17% in low-dose treatment, 78.57% in high-dose treatment. High-dose treatment is shown to alleviated corneal staining signs of dry eye patients comparably to placebo. Further evaluations would be needed for this mixture to demonstrate being a novel therapeutic agent for dry eye syndrome.

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Biography
Choun Ki Joo, MD, PhD has expertise in cataract, cornea, and other basic studies. He is a Dean of the College of Medicine, the Catholic University of Korea, and also President of the Catholic Institute for Visual Science.

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